



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/509,673

10/08/2004

Katsuyoshi Nagao

040520

6132

23850 7590 10/01/2009
KRATZ, QUINTOS & HANSON, LLP
1420 K Street, N.W.
Suite 400
WASHINGTON, DC 20005

EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

10/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,673	Applicant(s) NAGAO ET AL.	
	Examiner Philip R. Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/27/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3 and 5-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/09 has been entered.

Response to Amendment

In the reply filed 8/27/09, applicant amended claims 1 and 3. Claims 1, 3, and 5-25 are currently pending.

Claim Rejections - 35 USC § 102 / Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3, 5, 6, 9-12, 14-16, 17-20, and 22-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Larkin (US 4,602,910).

2. With respect to Claims 1, 3, 5, 6, 9-12, 15, 17-20, 23, and 25 Larkin teaches a multiple-chamber medical container comprising a container body having multiple chambers (between sheets 15 and 18 and between sheets 37 and 18, see Figure 3) that are capable of containing medicaments therein, and a partitioning seal that separates the first and second chambers from each other. The system further comprises a medicinal outlet portion attached to the container body for discharging the medicaments from the chamber therethrough, and an openable small container 36 having a medicament 50 (such as an antibiotic) therein positioned within the first chamber 18 (see Figure 5). The small chamber comprises a multi-layer film (Fig. 6) that is heat sealed and is structured to open in response to external force, and has a bonded portion 44 bonded to the container body, wherein the bonded portion comprises opposing outer surfaces of sheet material, wherein the opposing outer surfaces are each bonded to the opposing inner wall surfaces of the container body in the vicinity of the partitioning seal portion. The small container is positioned partly inserted into the partitioning seal portion and is opened in accordance with the separation of the walls (15, 18) of the container body.

Art Unit: 3761

With specific regard to the recitation that the partitioning seal is formed by separably bonding opposing inner wall surfaces of the container body, the claimed phrase is being treated as a product by process limitation; that is, that the partitioning seal is formed by separably bonding opposing inner wall surfaces of the container body. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Larkin is silent as to the process used to create the partition seal, it appears that the product in Larkin would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of a flexible plastic material that is bonded together at certain points to create a plurality of chambers.

3. With respect to Claims 14 and 22, Larkin teaches a mandrel-type seal 32 to prevent discharge of fluid until the seal is broken.

4. With respect to Claims 16 and 24, the bag of Larkin is fully capable of being placed inside a bag and arranged in any position. If applicant amends the claims to add structure to the bag, the examiner reserves the right to impose a restriction requirement between the bag and the container.

Art Unit: 3761

5. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin in view of Inoue (US 5,423,421). Larkin teaches the device substantially as claimed, but does not specifically disclose that the seal comprises a plurality of bonded parts arranged with at least one non-bonded part therebetween. Inoue discloses a multichamber container for mixing medical fluids, wherein a small container is fluidly connected to a large container by a separable bonded section. The bonded section is configured such that it becomes delaminated when sufficient pressure is applied (see figure 4). Furthermore, the bonded section comprises a non-bonded portion 9 in the center of the bonded portion. This configuration reduces the amount of sealing that is performed, thereby reducing the strength of the seal to make it easier to open, and eliminates the likelihood that the sealing operation will thermally degrade the medicinal preparations accommodated in the chambers (Column 4, Line 63 through Column 5, Line 37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medicament mixing device of Larkin with the unsealed portion of the bonded section of Inoue in order improve the breakability of the seal and prevent heat damage to the medicaments stored within the device.

6. Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin in view of Becker (US 6,319,243). Larkin teaches the device substantially as claimed, but does not specifically disclose that the small container is disposed in the same chamber as the outlet portion. Becker discloses a multichamber container for mixing medicaments, wherein a plurality of breakable seals (18, 20) are positioned

Art Unit: 3761

between the chambers, therefore allowing selective mixing of the chambers (see Figures 1 and 2). Becker further discloses a plurality of outlets (31, 32, 34) (one in each chamber), such that fluid may be selectively drained from any of the chambers. This would allow, for example, fluids from two of the three chambers to be mixed together and drained, without mixing the fluid with the third chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medical fluid mixing device of Barney and Larkin with Becker's use of a plurality of fluid outlets (i.e. one in each chamber), such that fluids could be mixed and drained in a variety of ways. It may not always be desirable to mix all the medicaments together, and placing an outlet in the same chamber as the smaller chamber would allow those fluids to be selectively mixed.

Response to Arguments

Applicant's arguments with respect to the rejection(s) of claim(s) 1, 3, and 5-25 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of new interpretation of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
29 September 2009